

510(k) Summary

Submitter and Contact Person:

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Director of Administrative Services
PDS Healthcare Products, Inc.
908 Main Street
Louisville, Colorado 80027
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Trade Name:

KoKo Peak KP and KP+

Common Name:

Peak flow meter

Classification Name:

Peakflow meter for spirometry [21 CFR 868.1860]

Predicate Device:

AirWatch II Zone [K982676] from ENACT Health Management Systems, Inc.

Description of Device:

The KoKo Peak are pocket-sized, battery-powered, personal electronic devices that measure peak expiratory flow (PEF) rate in liters per minute and forced expiratory volume in one second (FEV1) in liters (KP+ only).

The KoKo Peak include an LCD for displaying PEF and FEV1 information to the consumer, a single control button, a removable mouthpiece, and an optical data port for downloading data from memory.

Indications for Use:

These peak flow meters measure the rate and amount of airflow through their mouthpiece. Intended for peak flow monitoring—"providing a simple, quantitative, and reproducible measure of the existence and severity of airflow obstruction"^[1]—the KoKo Peak can be used at home by consumers older than 4 years "for short-term monitoring, managing exacerbations, or daily long-term monitoring"^[1] of chronic respiratory conditions, especially asthma.

Summary of Technological Characteristics:

The one technological difference between the KoKo Peak and their predicate device is the means by which they sense the airflow. The flow sense mechanism of the KoKo Peak uses

¹ National Asthma Education and Prevention Program. *Expert panel report 2: Guidelines for the diagnosis and management of asthma*. Pub 97-4051. Bethesda MD: National Institutes of Health, 1997.

a cantilever beam in the air stream instead of a turbine in the flow.

Both flow sense technologies are used in numerous commercial applications for airflow sensing. The advantage of the cantilever-beam method is increased resolution at low flow rates, but both meet the performance requirements of the American Thoracic Society² for peak flow monitoring applications.

Summary of Non-Clinical Performance Data:

The KoKo Peak and their predicate device meet recognized safety standards. The predicate device meets all applicable electrical, mechanical and environmental safety requirements given in the Reviewers Guidance for Premarket Notification Submissions, Appendix A (1993). The KoKo Peak meets similar, but more extensive, requirements from recognized consensus standards for safety of medical electrical equipment: IEC 601-1:1988 with amendments for safety and IEC 601-1-2:1993 for electromagnetic compatibility.

Performance of the KoKo Peak and its predicate device meets or exceeds recognized industry standards: conforming to the National Asthma Education and Prevention Program's requirement for meters for peak flow monitoring¹ by meeting the American Thoracic Society recommendations for monitoring devices².

The KoKo Peak were also tested using specialized flow waveforms as part of a validation/ measurement-quality study. The study demonstrated that the KoKo Peak KP+ can appropriately provide information regarding a subject's PEF and FEV1 measurements (and PEF for the KP) and can appropriately identify PEF measurements of suspect quality.

Summary of Clinical Performance Data:

The KoKo Peak KP and KP+ was tested on 8 study subjects (6 adults and 2 children) in a study of home use and user guide effectiveness.

In summary, the studies demonstrated that consumers can safely and effectively use the KoKo Peak under conditions of actual use; that consumers can interpret KoKo Peak's display readings and take appropriate actions; and that KoKo Peak's user guide, physical design, and other human factors characteristics are appropriate for consumers.

Technical Specifications:

- Dimensions: (120 x 50 x 20) mm
- Weight: 82 g
- Temperature Range: 10°C to 38°C
- Storage Temperature: -20°C to 60°C
- Operating Humidity: 0% to 100%, non-condensing
- Display: LCD Display
- Power: Two 1.5-volt silver-oxide batteries
- Battery Symbol: Low Battery
- Battery Life: Approximately 1 year with an average daily usage of 3 test sessions per day
- Memory Capacity: 64 test sessions (maximum)
- Data port: Infrared optical

² American Thoracic Society. Standardization of spirometry: 1994 update. *Am J Respir Crit Care Med* 152:1113-5, 1995.



JUN - 1 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cheryl Railsback
PDS Healthcare Products, Inc.
908 Main Street
Louisville, CO 80027

Re: K010009
KoKo Peak KP and KP+
Regulation Number: 868.1860
Regulatory Class: II (two)
Product Code: 73 BZH
Dated: March 22, 2001
Received: March 27, 2001

Dear Ms. Railsback:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

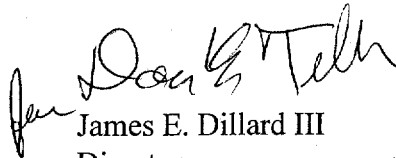
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further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III

Director

Division of Cardiovascular and
Respiratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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510(k) Number (if known): _____

Device Name: KoKo Peak

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)


Division of Cardiovascular & Respiratory Devices
510(k) Number K010009/51